

**In the Arbitration under the Arbitration Rules of the
United Nations Commission on International Trade Law and
the North American Free Trade Agreement
(Case No. UNCT/14/2)**

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

EXPERT REPORT OF MURRAY WILSON

I. INTRODUCTION

1. My name is Murray Wilson and I reside in the City of Ottawa, Ontario.
2. I confirm that I have no relationship to Eli Lilly and Company or any of its affiliates.
3. I worked for the Canadian Patent Office for over 35 years as a patent examiner and in various other capacities such as the acting Chair of the Patent Appeal Board. Based upon that experience, I believe that I am qualified to provide the factual information and opinions set out below.
4. During my 35 year career with the Canadian Patent Office I examined and reviewed thousands of patent applications, including pharmaceutical patents. I have extensive experience and in-depth knowledge about the Canadian Patent Office practice relating to the examination and granting of patents during the time period the Strattera and Zyprexa patent applications were examined and the patents granted (patent 2,209,735 and patent 2,041,113, respectively).
5. After graduating from Carleton University in 1971 with a Bachelor of Mechanical Engineering Degree, I started working in the Canadian Patent Office in 1971 as a patent examiner in the Mechanical Division, examining patent applications in the material handling arts.
6. In 1981, I became a senior patent examiner with responsibilities for examining patent applications that were filed in French.
7. In 1982, I was appointed Assistant to the Commissioner of Patents/Registrar of Trade-marks.
8. In 1987, I became a project officer in the Policy and Program Planning Branch of the Canadian Intellectual Property Office. This position had various duties including responsibility for the formal training of all new patent examiners.

9. In 1992, I became a member of the Patent Appeal Board. The Patent Appeal Board reviews the prosecution of patent applications which have been rejected during the patent examination process and makes recommendations to the Commissioner of Patents as to whether the examiner's rejection should be upheld or reversed. If the Commissioner refuses the application, the patent applicant can appeal to the Federal Court. The Board members were also responsible for the preparation of conflict awards pursuant to section 43(7) of the *Patent Act*.¹ In 2006 I became acting Chair of the Patent Appeal Board and remained in that position until I retired in 2008.

10. I was Chairman of the Patent Agent Examination Board and the Trade-mark Agent Examination Board from 1994 to 2008. These Boards are responsible for the setting, marking and administration of examinations that individuals must pass in order to become a registered patent agent or a registered trade-mark agent. The Patent Agent Examination Board is constituted in accordance with section 13 of the *Patent Rules*.² The Chair and at least three other members are employees of the Patent Office and at least five members are patent agents nominated by the Intellectual Property Institute of Canada.

11. I was delegated by the Commissioner of Patents, in consultation with the Minister of Industry, to carry out the powers of the Commissioner pursuant to sections 66, 68-69 of the *Patent Act* (abuse of patent rights)³ from May, 2004 until I retired.

II. INSTRUCTIONS

12. I have been asked to provide testimony about the following matters:

- (i) explain the patent examination process at the Patent Office;
- (ii) explain the purpose of the *Manual of Patent Office Practice* ("MOPOP")
- (iii) explain the guidance in *MOPOP* provided to patent applicants and patent examiners about the utility requirement for obtaining a patent at the time the Zyprexa patent was granted and review the Zyprexa file wrapper;

¹ Patent Act (Canada), R.S.C. 1985, c. P-4, as am., § 43(7) (C-50).

² Patent Rules (Canada), SOR/96-423 (C-51).

³ Patent Act (Canada) §§ 66, 68-69 (2003) (C-52).

- (iv) explain the guidance in *MOPOP* provided to patent applicants and patent examiners about the utility requirement for obtaining a patent at the time the Strattera patent was granted and review the Strattera file wrapper.

III. THE PATENT EXAMINATION PROCESS

13. The Patent Office employs a corps of examiners who are selected and hired based on aptitudes and previous scientific training. All patent examiners hold either an engineering degree or an honours degree in science, with some examiners holding advanced degrees at the Masters or Ph.D. level.

14. Examiners receive about three months of in-class training and receive course materials relating to the main requirements for obtaining a patent (e.g. utility). Trainees initially work under the supervision of senior examiners.

15. During substantive examination, examiners are required and trained to thoroughly screen and examine applications for conformity with the *Patent Act* and *Patent Rules*. The main tenets of examination are the analysis by the examiner as to the novelty, utility and non-obviousness of the claimed invention. During training course materials are provided to examiners, which included the legal requirements for granting a patent.

16. The examiner also verifies that the description of the invention is sufficient to allow others to practice the invention. Only patent applications which meet all of the requirements of the patent legislation are allowed to issue into patents since granted patents are presumed to be valid under the *Patent Act*.

17. If the examiner identifies problem areas with any portion of the application, for example in the specification, drawings, abstract or claims, an examiner's report is issued. This report, commonly referred to as an Office Action, explains why the application is not compliant. To the best of my recollection, an Office Action would rarely raise an issue regarding the utility requirement to obtain a grant of a patent.

18. The applicant is provided with an opportunity to respond to and amend the application to overcome an examiner's rejection with the caveat that new subject matter cannot be added to the application. This interaction between the applicant and the Patent Office can

repeat itself until the examiner decides that the application complies with the *Patent Act* and the *Patent Rules* and allows the application or the examiner rejects the application in an Examiner's Final Action. Often the examiner will issue no more than two or three Office Actions before issuing a Final Action. If the examiner allows the application, a notice of allowance is sent to the applicant ultimately resulting in the grant of a patent by the Commissioner of Patents. The grant of a patent is not an "initial" grant – there is only one grant of the patent and the grant is presumed valid by the *Patent Act*.

19. Rejected applications can be referred to the Patent Appeal Board for a Commissioner's Decision. The Patent Appeal Board can make a recommendation to the Commissioner of Patents to reverse the examiner's Final Action or to affirm the Final Action.

20. In my experience, the fact that the U.S. or U.K. patent office had granted a patent to an identical invention was of some influence to Canadian patent examiners. International patent applications filed under the PCT were also easier to review because they included a search report, which meant the examiner did not have to spend as much time searching the prior art.

IV. ROLE OF THE MANUAL OF PATENT OFFICE PRACTICE (“MOPOP”)

21. Patent examination is governed by the *Patent Act* and the *Patent Rules*. The Canadian Intellectual Property Office's Manual of Patent Office Practice provides guidance to examiners.

22. Although MOPOP is to be considered solely as a guide, in my experience, MOPOP recorded the Patent Office's practice and was tantamount to a rulebook to be followed by patent examiners and patent agents during the prosecution of applications filed with the Patent Office.

23. MOPOP was first published in 1979. MOPOP has been revised to reflect amendments to the *Patent Act* and court decisions that impact examination and administrative procedures. The process of amending MOPOP often involves significant discussions and review by Department of Justice lawyers and consultation with the patent profession before new court decisions are incorporated into the Manual.

24. The MOPOP chapters addressing utility and description—as related to utility—were revised in 1990, 1996, 1998, 2005, 2009 and 2010.⁴

25. There were no changes made to MOPOP with respect to the utility requirement between 1990 and 1996. As discussed below, significant changes were made to the utility requirement in the amendments to the 2009 and 2010 MOPOP.

V. UTILITY REQUIREMENTS IN EFFECT AT THE TIME THE ZYPREXA AND STRATTERA PATENTS WERE GRANTED

26. In November 1987, Canada started to provide patent protection to pharmaceutical compounds. Prior to that date, pharmaceuticals were only eligible for product by process patents. Going forward, the Patent Office evaluated pharmaceutical composition patents under the same utility standard as other inventions.

27. During my tenure at the Patent Office, there was a low threshold for establishing utility of a claimed invention. Patent examiners' review of whether an applicant meet the utility requirement was quite simple. Examiners' scrutiny primarily fell instead on the novelty and non-obviousness requirements. For utility, the question examiners asked was purely whether there was reason to doubt that the invention would work. If in doubt, examiners could ask for working models. If the claimed invention worked or could work for any particular purpose, then it had utility. An invention was either useful or it was not. There was no requirement that an invention have a particular amount of utility.

28. If the utility of the invention was not apparent, the patent applicant would be required to disclose how the invention would be useful. I was aware of applications that were denied for lack of utility, but in these cases the inventions were found inoperable or unworkable. For instance, patent applications for a machine to burn water, a death ray machine, and a perpetual motion machine were rejected.

29. However, examiners did not consider advantages of the invention that were stated in the disclosure to be equivalent to the utility of the invention. Examiners would not

⁴ The chapters of the MOPOP from each of these years can be found at exhibits C-53 to C-60.

comb through patent application to identify claims or assertions as to why an invention was better than previous inventions. They were only looking for any utility, for example if a drug would be useful to treat schizophrenia or ADHD. There had to be some indication of what the invention would be used for, however, additional benefits of the type frequently described by an applicant—such as if the drug had fewer side-effects, was easier to manufacture, or could be taken less often—were not construed as part of the “utility” of the invention. While these assertions may contribute to the explanation of why the invention is “inventive,” they were not considered in determining whether the invention was useful.

30. Examiners generally would accept credible assertions made by the patent applicant with respect to the intended utility. Following *Monsanto Co. v. Canada (Commissioner of Patents)*⁵, a Supreme Court of Canada case that determined that claims to untested compounds could be made on the basis of a sound prediction, patent examiners were instructed to accept credible assertions as to predicted utility. Unless the examiner had reason to doubt that the invention worked, the inquiry ended there. As a result, it was neither required nor typical for applicants to provide much, if any, data derived from real world use, whether through clinical data of pharmaceuticals, or through road testing of machines. In sum, there was a low bar to meeting the utility requirement prior to the 2009 and 2010 changes to MOPOP. In my experience sitting on the Patent Appeal Board from 1992-2008, I cannot remember a pharmaceutical patent that was rejected for lack of utility.

A. Olanzapine (Zyprexa)

1. MOPOPs in Effect at Time of Zyprexa Patent Examination

31. Eli Lilly filed its patent application for olanzapine (Zyprexa) in April, 1991 and requested examination in October, 1995. The olanzapine (Zyprexa) patent was granted on July 14, 1998 (patent 2,041,113).

32. The relevant sections of MOPOP relating to utility when the olanzapine (Zyprexa) patent was examined was the 1990 MOPOP Chapter 12:

⁵ [1979] 2 S.C.R. 1108 (C-61).

12.02.01

An invention must be useful

Section 2 of the Act requires utility as an essential feature of invention. If an invention is totally useless, the purposes and objects of the grant would fail and such grant would consequently be void on the grounds of false suggestion, failure of consideration and having tendency to hinder progress (Northern Electric Co. Ltd. v. Browns Theatres Ltd. (1940) Ex. Cr., (1941) S.C.R.)

12.02.02

Utility must be disclosed

An application for patent must not only describe the invention, but also its operation or use (Section 34(1)). The operation or use of the invention must, of course, show the purpose for which the invention was intended. An invention may have several uses, but it must always have at least one.

The claims must be drafted to an invention having the utility disclosed. If the claims cover only things that have utility other than that disclosed or if they include inoperable and therefore useless embodiments, they are bad (O' Cedar v. Mallory (1956) Ex. C.R. 299).

12.03

PREREQUISITES OF A PATENTABLE INVENTION

Utility, as related to inventions, means industrial value. To be acceptable in the patentable sense, it must be something that will impart industrial value to what is sought to be patented (Northern Electric v. Browns Theatres supra).

In assessing whether subject matter falls within the meaning of the definition of a patentable invention under Section 2 of the Patent Act, the prerequisites established by Canadian jurisprudence and legislation that must be satisfied are, inter alia:

(a) whether the subject matter relates to a useful art (as distinct from a fine art where the result produced is solely the exercise of personal skills, mental reasoning or judgment, or has only intellectual meaning or aesthetic appeal);

(b) whether the subject matter is operable, controllable and reproducible by the means described by the inventor so that the desired result inevitably follows whenever it is worked;

(c) whether the subject matter has practical application in industry, trade or commerce;

(d) whether it has a licit object in view (Section 27(3));

(e) whether it is more than a mere scientific principle or abstract theorem (Section 27(3)) and

(f) whether it is beneficial to the public.⁶

33. The relevant MOPOP dealing with the description section of the patent when the olanzapine (Zyprexa) patent was examined was Chapter 9 of the 1996 MOPOP. The portions of that chapter relevant to utility were:

**9.01
THE DESCRIPTION**

...The description must describe the invention and its operation or use as contemplated by the inventor (subsection 27(3) of the Patent Act)...Under Section 2 of the Patent Act, the invention must have utility. The description should explain at least one use of the invention in sufficient detail to enable a skilled person to use the invention for its intended purpose. If no use can be seen on the basis of the description, the application may be rejected for lack of utility.⁷

2. Review of Zyprexa File Wrapper

34. I have reviewed the Canadian Patent Office's file wrapper (the examination history) for patent 2,041,113 (Zyprexa/olanzapine).⁸

35. On April 1, 1997, the examiner in charge of the application issued the only Office Action on this application.⁹ In it she cited two British patents to reject claims 1 to 7 for lack of novelty. She also rejected some claims as being indefinite and she required the applicant to supply a new title for the application. Finally, she asked for details of the prosecution of the corresponding United States and European applications.

36. There was no mention of any problems with the way in which Eli Lilly set out the utility of the invention. On September 5, 1997 the applicant responded to the Office Action

⁶ Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, §§ 12.02.01-12.02.02, 12.03 (January 1990) (C-53).

⁷ Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, § 9.01 (October 1996) (C-55).

⁸ File History for patent 2, 041,113 (Zyprexa/olanzapine) (C-62).

⁹ Office Action re Application No. 2,041,113 (April 1, 1997) (C-63).

and amended the application to satisfy the examiner's objections.¹⁰ A Notice of Allowance was issued in 1998 and the patent was granted.¹¹

37. Based on my experience, patent examiners will raise all potential concerns or errors with a patent application in an Examiner's Report. Here, the examiner did not raise any issues with utility in the Report. Instead, the Report dealt with separate questions of novelty, indefinite claims, and title. If the examiner had any questions about utility, those concerns would have been raised in the Report. The examiner found that the '113 patent application clearly met the utility requirements.

38. Based on my independent evaluation of the Zyprexa file wrapper and the '113 patent, Lilly fulfilled MOPOP's requirements for utility existing at the time the patent was granted.

B. Atomoxetine (Strattera)

1. MOPOPs in Effect at Time of Strattera Patent Examination

39. Eli Lilly filed its patent application for atomoxetine (Strattera) in 1996 and requested examination in February, 2001.¹² The atomoxetine (Strattera) patent was granted in October 1, 2002 (patent 2,209,735).¹³

40. The relevant section of MOPOP relating to utility when the atomoxetine (Strattera) patent was examined was the 1998 MOPOP, Chapter 16:

16.02.01

An Invention Must Be Useful

Section 2 of the Patent Act requires utility as an essential feature of invention. Utility, as related to inventions, means industrial value. If an invention lacks utility for its described purpose it will result in an invalid patent should it be granted. The use of the invention must be apparent from the description to one skilled in the art.

¹⁰ Response to Office Action re Application No. 2,041,113 (September 5, 1997) (C-64).

¹¹ Notice of Allowance re Application No. 2,041,113 (March 17, 1998) (C-65).

¹² Request for Examination for Application 2,209,735 (Strattera/atomoxetine) (February 27, 2001) (C-66).

¹³ Patent No. 2,209,735 (C-67).

16.03

PREREQUISITES OF A PATENTABLE INVENTION

In assessing whether subject matter falls within the meaning of the definition of a patentable invention under Section 2 of the Patent Act, the prerequisites established by Canadian jurisprudence and legislation that must be satisfied are, *inter alia*:

- (a) whether the subject matter relates to a useful art (as distinct from a fine art where the result produced is solely the exercise of personal skills, mental reasoning or judgment, or has only intellectual meaning or aesthetic appeal;
- (b) whether the subject matter is operable, controllable and reproducible by the means described by the inventor so that the desired result inevitably follows whenever it is worked;
- (c) whether the subject matter has practical application in industry, trade or commerce and
- (d) whether it is more than a mere scientific principle or abstract theorem (Section 27(8) of the Patent Act).¹⁴

41. The relevant section of MOPOP relating to the description section of the patent when the atomoxetine (Strattera) patent was examined was Chapter 9 of the 1998 MOPOP. The portions of that chapter relevant to utility were:

9.01

THE DESCRIPTION

...The description must describe the invention and its operation or use as contemplated by the inventor (subsection 27(3) of the Patent Act).... Under Section 2 of the Patent Act, the invention must have utility. The description should explain at least one use of the invention in sufficient detail to enable a skilled person to use the invention for its intended purpose. If no use can be seen on the basis of the description, the application may be rejected for lack of utility.¹⁵

2. Review of Strattera File Wrapper

¹⁴ Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, §§ 16.02.01, 16.03 (March 1998) (C-57).

¹⁵ *Id.* § 9.01 (C-56)

42. I have reviewed the Canadian Patent Office's file wrapper (the examination history) for patent 2,209,735 (Strattera/atomoxetine).¹⁶

43. The examiner in charge of this application did not issue an Office Action. The Notice of Allowance issued in 2002 and the patent was granted.¹⁷

44. In my experience, patent examiners are trained to raise every concern which they identify in an Examiner's Report and do not hesitate to raise concerns about patent applications. If there was any issue with respect to utility, it would have been raised in an Office Action. The examiner did not find any problem with the way in which Lilly set out the utility of the invention.

45. Based on my independent examination of the Strattera file wrapper and the '735 patent, Lilly fulfilled MOPOP's requirements for utility at the time the patent was granted. In particular, MOPOP did not require Lilly to disclose human clinical data completed prior to the filing of the application, such as the Massachusetts General Hospital clinical trial study.

VI. CHANGES TO THE UTILITY REQUIREMENT IN MOPOP AFTER THE PROMISE UTILITY DOCTRINE

46. Discussion of potential changes to MOPOP regarding the utility requirement started at the end of my tenure at the Patent Office, around 2007 and 2008. I remember it well because I had informal discussions with my colleagues about the suggested changes to the utility requirement which were a stark contrast to prior patent office practice. Before I left the Patent Office, examiners did not comb through applications to pick out every claim or "promise" of why an invention was better. Instead, they looked for any utility. This significantly changed, however, with the 2009 and 2010 MOPOP amendments..

47. Since MOPOP needs to reflect developments in the law, I was not surprised to see the 2009 and 2010 MOPOPs required significant changes to the utility doctrine in light of the court decisions on the promise utility doctrine.

¹⁶ File History for patent 2,209,735 (Strattera/atomoxetine) (C-68).

¹⁷ Notice of Allowance re Application No. 2,209,735 (March 21, 2002) (C-69).

48. The changes made in 2009 and 2010 contained extensive requirements for utility that did not exist when Eli Lilly applied for its olanzapine (Zyprexa) and atomoxetine (Strattera) patents. These changes remain in the latest version of MOPOP. For example, the current version of Chapter 12 of MOPOP, revised in 2009, contains the following language:

12.08.01

Operability

... Where, however, the inventors promise that their invention will provide particular advantages (e.g. will do something better or more efficiently or will be useful for a previously unrecognized purpose) it is this utility that the invention must in fact have.

Although an invention need only have one use in order to be patentable, where several uses are promised the applicant must be in a position to establish each of them.

12.08.04c

Proper Disclosure

The requirement for proper disclosure means that the person skilled in the art has to, through the specification alone, be provided with sufficient information to understand the basis of the sound prediction and to practice the entire scope of the claimed invention. Elements of either the factual basis or the sound line of reasoning that form part of the common general knowledge will not, as a general rule, need to be disclosed. Elements that form part of the state of the art could (depending on the specific circumstances) be properly disclosed merely by referring to the document in which they are contained. Elements known only to the inventors, however, need to be included in the description itself.

12.08.05

Relevant Date

The applicant must be in a position to establish the utility of their invention no later than at their filing date. Consequently, the factual basis upon which either the demonstration or sound prediction are based must necessarily exist as of the filing date. Similarly, if a sound prediction is to be relied upon, the articulable and sound line of reasoning referred to in 12.08.04 must also exist as of the filing date.

...¹⁸

¹⁸ Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, § 12.08.01, 12.08.04c, 12.08.05 (Dec. 2009) (C-59).

Chapter 9 of MOPOP, governing the description, was amended in 2010 and included the following language:

9.04.01a

Disclosure of the factual basis

The factual basis needed to render the line of reasoning sound must be disclosed. If some or all of the facts being relied on are found in another publicly available document, this document must be properly identified. Any necessary facts that are not otherwise publicly available must be included in the description.

...

9.04.01b

Disclosure of the sound line of reasoning

The person skilled in the art must also appreciate the sound line of reasoning that connects the factual basis to the conclusion that the invention has the promised utility.

Here again, the description must provide whatever explanation is necessary to supplement the common general knowledge of the person skilled in the art so as to permit them, in view of the factual basis provided, to soundly predict that the invention will have the utility proposed.

¹⁹
...

49. According to these amendments, examiners at the Patent Office must look not only at whether the applicant established one use for the claimed invention, but whether all advantages described in the disclosure were demonstrated or soundly predicted. Examiners are now required to closely scrutinize all of the statements in the description of the invention in assessing utility, which examiners did not do during the time period that the Zyprexa and Strattera patents were prosecuted and granted. The 2009 and 2010 MOPOP amendments also now require that applicants relying on sound prediction disclose all evidence of utility in the description. This limitation on how and when evidence of utility could be presented to the examiner did not exist at the time the Zyprexa and Strattera patents were prosecuted and granted.

¹⁹ Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, § 9.04.01a-9.04.01b (Dec. 2010) (C-60).

VII. CONCLUSION

50. The standard for utility, as set out in MOPOP at the time the Strattera and Zyprexa patents were examined and granted, was a low bar. At that time the Patent Office only required that an invention be useful and that one of its uses be disclosed. The examiners of the Zyprexa and Strattera applications would have been familiar with this standard and there was no mention of utility as an issue during their examinations. The Zyprexa and Strattera patent applications met the Canadian Patent Office's requirements as set out in MOPOP on the dates of the grants.

Signed at the City of Ottawa on September 25, 2014

[Signed]
MURRAY WILSON

Attachment A

MURRAY WILSON

OTTAWA, ONTARIO, CANADA

EXPERIENCE

1992 TO 2008 **CIPO – Patent Appeal Board**

- Acting Chair, 2006-2008.
- Member, 1992-2008
 - Served as chair of a majority of re-examination boards.
 - Responsible for preparing decisions for the Commissioner under section 21.01 of the Patent Act.
 - Delegated authority to carry out the powers of the Commissioner under sections 66, 68-69 of the Patent Act (abuse of patent rights).

1994 TO 2008 **CIPO – Patent Agent Examination Board**

- Chair, 1994-2008.
- The patent agent examination board is responsible for the administration of examinations for registered patent agents.

1994 TO 2008 **CIPO – Trade-mark Agent Examination Board**

- Chair, 1994-2008.
- The board is responsible for the administration of examinations for registered trade-mark agents.

1971 TO 1992 **CIPO – Patent Office**

- Project Officer, Policy and Program Planning Branch, 1987-1992.
- Assistant to the Commissioner of Patents and Registrar of Trade-marks, 1982-1987.
- Senior Patent Examiner, 1981-1982.
- Patent Examiner, 1971-1981.

EDUCATION

B.S. (MECH. ENG.) Carleton University, Ottawa